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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ACCORD HEALTHCARE INC., Defendant.	Civil Action No. 13-XXXX (XXX) (XXX)

COMPLAINT

1. Plaintiff Novartis Pharmaceuticals Corporation ("Novartis") alleges as follows on personal knowledge as to its own actions and observations, and on information and belief as to all other facts.

NATURE OF THE ACTION

2. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 that arises out of Defendant's requests for approval from the U.S. Food and Drug Administration ("FDA") to manufacture and sell generic versions of Novartis's Zometa® prior to the expiration of U.S. Patent No. 8,324,189 ("the '189 patent").

THE PARTIES

A. Novartis

3. Plaintiff Novartis is a corporation organized under Delaware law. Its principal place of business is in East Hanover, New Jersey. Novartis owns the '189 patent.

B. Accord Healthcare Inc.

4. Accord Healthcare Inc. ("Accord") is a corporation organized under North Carolina law. Its principal place of business is 1009 Slater Road, Suite 210-B, Durham, North Carolina, 27703.

5. Upon information and belief, Defendant Accord has systematic and continuous contacts with New Jersey, including engagements to strategically develop, market, deliver, and/or sell generic products in New Jersey. In addition, Defendant Accord has previously acquiesced to personal jurisdiction and asserted counterclaims in this District.

6. Upon information and belief, Defendant Accord submitted to the FDA Abbreviated New Drug Application (ANDA) No. 205279 seeking approval to a market generic version of

Zometa.[1]

JURISDICTION AND VENUE

7. This action seeks to enforce federal patent rights under federal law. Accordingly, this Court has federal question jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and declaratory judgment jurisdiction under 28 U.S.C. §§ 2201 and 2202.

8. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b).

9. This Court has personal jurisdiction over the defendant for the following reasons, among others:

a) The defendant has sold generic drugs in New Jersey, and is seeking approval to sell and/or distribute a generic version of Zometa in New Jersey;

b) Novartis, which will be harmed by the defendant's actions, is domiciled in New Jersey; and

c) Defendant Accord has systematic and continuous contacts with New Jersey, in that, among other things, it sells, manufactures, imports and/or distributes generic drugs in New Jersey

d) Defendant Accord has previously acquiesced to personal jurisdiction and asserted counterclaims in this District.

STATEMENT OF FACTS

A. Novartis's Branded Products

10. The active ingredient in Zometa is zoledronic acid. Zometa was first approved by the FDA in 2001 and is approved to treat hypercalcemia of malignancy (HCM), a condition resulting in high calcium blood levels due to cancer, multiple myeloma and bone metastases from solid

[1] Although ANDA No. 205279 was purportedly submitted by a company called "Accord Healthcare Inc., USA," no such corporate entity appears to exist.

tumors. Zometa's primary indication is for the prevention of skeletal-related complications associated with cancer, such as fractures and pain.

11. Zometa is administered intravenously as a 4 mg dose of zoledronic acid diluted in standard buffer media. Zometa has been sold in three forms: (a) a "pre-concentrate" vial of 4 mg of Zometa diluted in 5 mg of buffer, which must be further diluted before administration to a patient; (b) a "Ready to Use" or "RTU" vial of 4 mg of Zometa in fully diluted form; and (c) a 4 mg vial of powder, which would be diluted by an infusion center before administration to a patient (this product was discontinued in 2003).

B. The Patent-In-Suit

12. The '189 patent, entitled "Use of zolendronate for the manufacture of a medicament for the treatment of bone metabolism diseases," was duly and legally issued on December 4, 2012, and is owned by Novartis. During clinical trials of Zometa, Novartis scientists learned that cancer patients could suffer renal toxicity—*i.e.* kidney damage—if the drug were administered too quickly. After extensive clinical experimentation, however, Novartis scientists discovered that renal toxicity could be controlled if Zometa were administered as a 4 mg dose over a 15 minute period. The '189 patent is directed to this method of treatment. A copy of the '189 patent is attached as Exhibit A.

13. Zometa and its methods of use are covered by the '189 patent, which has been listed in connection with Zometa in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, which is also referred to as the "Orange Book." Accordingly, the defendant has actual or constructive knowledge of the patent.

C. The ANDA Process

14. The FDA regulates the manufacture, sale and labeling of prescription drugs in the

U.S. Under the 1984 Hatch-Waxman Act, companies wishing to bring a generic version of a branded prescription drug to market can submit an ANDA to the FDA. 21 U.S.C. § 355(j). This ANDA process allows the generic drug maker to avoid the expensive clinical trials required of an NDA holder to demonstrate a drug's safety and effectiveness. The generic company simply relies on the original NDA submission for that purpose.

15. The Hatch-Waxman Act also contains provisions meant to balance the interests of branded and generic companies in resolving claims concerning the branded company's patents. The Act requires drug makers to identify the patents covering their drugs in the Orange Book. 21 U.S.C. § 355(b)(1)(c)(2). When seeking ANDA approval, the applicant must take certain actions with respect to listed patents.

16. Under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), an applicant can assert that the branded drug's Orange Book patent(s) is/are invalid, unenforceable, and/or will not be infringed, a so-called "Paragraph IV certification." Such a certification is provided to the FDA and notice is given to the NDA holder and patent owner. Upon receiving notice of the certification, the NDA holder or patent owner can choose to enforce its patents in federal court.

D. The Generic's ANDA Application

17. As noted above, Defendant Accord has submitted an ANDA seeking approval to manufacture and sell generic versions of Zometa.

18. By letter dated March 14, 2013, Defendant Accord notified Novartis that it had submitted to the FDA ANDA No. 205279 for a generic version of Zometa. Based on that Paragraph IV notice letter, on April 12, 2013, Novartis sued Accord. However, in September 2013, Accord for the first time represented to Novartis that the FDA had not yet notified Accord that its ANDA was acceptable for filing.

19. On October 28, 2013, Accord's counsel informed Novartis's counsel that it received notice from the FDA, by letter dated October 21, 2013, that Accord's ANDA was acceptable for filing.

20. By letter dated November 8, 2013, Defendant Accord notified Novartis that it had submitted to the FDA ANDA No. 205279 for a generic version of Zometa.

21. With respect to ANDA No. 205279, which seeks approval to market a generic version of Zometa, Defendant Accord stated that its ANDA included certifications pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) with respect to the '189 patents, alleging that they are invalid and/or will not be infringed by the commercial manufacture, use, offer for sale or sale of the Defendant Accord's generic Zometa products.

22. This action is being commenced before expiration of forty-five days from Novartis's receipt of the properly served Paragraph IV notice letter, dated November 8, 2013.

COUNT I (INFRINGEMENT OF THE '189 PATENT)

23. Each of the preceding paragraphs 1 to 22 is incorporated as if fully set forth herein.

24. The use of Defendant Accord's generic Zometa is covered by one or more claims of the '189 patent.

25. Upon information and belief, Defendant Accord knew of the '189 patent when it submitted ANDA No. 205279, and knows or is willfully blind to the fact that its actions will induce or contribute to direct infringement of the '189 patent.

26. Defendant Accord's submission of ANDA No. 205279, for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of its Zometa products before the expiration of the '189 patent is an act of infringement of the '189 patent under 35 U.S.C. § 271(e)(2).

27. Use of Defendant Accord's generic Zometa products in accordance with and as directed by Defendant Accord's proposed labeling for those products would infringe one or more claims of the '189 patent.

28. Upon information and belief, upon FDA approval of its ANDA, Defendant Accord will indirectly infringe the Zometa patent by making, using, offering to sell, and selling its zoledronic acid solution containing 4 mg zoledronic acid as the active ingredient in the United States and/or importing such a solution into the United States.

29. Upon information and belief, Defendant Accord will actively induce infringement of the '189 patent in violation of 35 U.S.C. § 271(b) when its ANDA is approved.

30. Upon information and belief, Defendant Accord knows that its generic Zometa products and its proposed labeling are especially made or adapted for use in infringing the '189 patent, and that its generic Zometa products and its proposed labeling is not suitable for substantial noninfringing use.

31. Upon information and belief, Defendant Accord plans and intends to, and will, contribute to the infringement of the '189 patent immediately and imminently upon approval of its generic Zometa products in violation of 35 U.S.C. § 271(c).

32. There is an actual and justiciable case or controversy between Novartis and Defendant Accord concerning the validity and infringement of the '189 patent. Novartis is entitled to a declaration that Defendant Accord's manufacture, use, sale, offer for sale, and/or importation of its generic Zometa drug products will infringe, contribute to the infringement of and/or actively induce the infringement of one or more claims of the '189 patent, and that the claims of the '189 patent are not invalid.

33. Unless Defendant Accord is enjoined from infringing the '189 patent, actively

inducing infringement of the ‘189 patent, and/or contributing to the infringement by others of the ‘189 patent, Novartis will suffer irreparable injury. Novartis has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Novartis requests entry of judgment in its favor and against defendant as follows:

1. Declaring that the’189 patent is not invalid;

2. Declaring that the Defendant has infringed, directly or indirectly, one or more claims of the’189 patent;

3. Damages or other monetary relief to Novartis if defendant engages or continues to engage in commercial manufacture, use, offers to sell, sale, or importation into the United States of generic versions of Zometa prior to the latest expiration date of the’189 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled;

4. Declaring that the Defendant by engaging in the commercial manufacture, use, offer to sell, sale, or importation into the United States of generic versions of Zometa has willfully infringed the claims of the’189 patent;

5. An order permanently enjoining Defendant, and its affiliates, subsidiaries, officers, agents, servants and employees and those acting in privity or in concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States generic versions of Zometa until after the latest expiration date of the patent relating to approved presentations, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled; and

6. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

DATED: November 26, 2013

s/ William J. O'Shaughnessy
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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I certify that to the best of my knowledge, the matter in controversy is the subject of:

- *Novartis Pharmaceuticals Corporation et al. v. Wockhardt USA LLC et al.*, Civil Action No. 2:12-cv-03967-SDW-MCA (consolidated) filed on June 27, 2012 in the District of New Jersey.

- *Novartis Pharmaceuticals Corporation et al. v. Akorn et al.*, Civil Action No. 2:13-cv-05125-SDW-MCA filed on August 26, 2013 in the District of New Jersey.

- *Novartis Pharmaceuticals Corporation et al. v. Akorn et al.*, Civil Action No. 2:13-cv-06835-SDW-MCA filed on November 8, 2013 in the District of New Jersey.

Dated: November 26, 2013

Respectfully Submitted,

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